

REMARKS

The office action dated December 17, 2004 has been carefully reviewed. Claims 1-13 are pending in this application. Claims 11 and 12 have been withdrawn. Reconsideration of this application is respectfully requested.

CLAIM REJECTIONS BASED ON §103

Claims 1-10 and 13 were rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,645,594 issued to Devanathan et al. (hereinafter "Devanathan"). Applicants respectfully traverse this rejection. Reconsideration of claims 1-10 and 13 is respectfully requested.

Discussion Re: Patentability of Claim 1

Claim 1, as filed, is as follows:

I. A method of making an implantable bearing for an orthopaedic prosthesis, comprising the steps of:  
providing a first layer constructed of a polymer;  
providing a second layer constructed of a copolymer comprising ethylene and an acrylate;  
securing said first layer to said second layer so as to create a composite; and  
forming said composite into a predetermined shape of said implantable bearing.

In the 12/17/04 Office Action, the Examiner indicates that Devanathan "do not teach using a copolymer of ethylene and acrylate", and asserts that "[i]t is well-known in the molding art that a copolymers and a blend of two materials are substitutable alternatives." The Examiner further indicates that "[t]hus, it would have obvious...to substitute the blend of Devanathan et al with a copolymer of ethylene and acrylate since they are substitutable alternatives." Apparently, in an attempt to arrive at the invention of Applicants' claim 1, the Examiner is modifying the method of Devanathan to use a

copolymer comprising ethylene and an acrylate in lieu of a blend of UHMWPE and PMMA to form the second layer of the bearing.

It is a fundamental tenet of patent law that a prima facie case of obviousness cannot be established in the absence of some teaching, motivation, or suggestion supporting the modification of the reference relied upon in making the rejection. The teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

In an apparent attempt to establish a case of obviousness in the present case, the Examiner stated that it would have been obvious to substitute the claimed "copolymer comprising ethylene and an acrylate" for the blend of UHMWPE and PMMA disclosed in Devanathan "since they are substitutable materials." However, this conclusory statement is completely devoid of any legally sufficient teaching, motivation, or suggestion to modify the bearing fabrication methods of Devanathan in the manner proposed by the Examiner. Even if, for arguments sake, the Examiner's assertion that "they are substitutable materials" were true, such a fact would not *ipso facto* create a prima facie case of obviousness. Indeed, the standard for obviousness is not merely whether the two materials are "substitutable", but rather the standard is whether the substitution would have been obvious under the statute (i.e., 35 U.S.C. § 103). See *In re Grabiak*, 769 F.2d 729, 226 USPQ 870 (Fed. Cir. 1985) ("Even though it may not be inconceivable to substitute sulfur for oxygen to obtain compounds having the same

expected properties, that is not the standard; the standard is whether it would have been obvious in terms of 35 U.S.C. § 103"). In the present case, the Examiner appears to be relying solely on the assertion that the two materials are "substitutable" as a basis for obviousness. However, the reliance on such a conclusory statement is not a legally sufficient substitution for the required factual analysis. In other words, even if the Examiner could show that the two materials are "substitutable" (which he has not attempted to do), such a showing would not in and of itself be a complete, legally sufficient analysis to support a finding of obviousness, but rather such a showing would only constitute a portion of such an analysis.

Furthermore, not only has the Examiner not offered a legally sufficient teaching, motivation, or suggestion to modify the bearing fabrication method of Devanathan, it is believed that no such motivation exists. Indeed, Applicants respectfully disagree with the Examiner's assertion that "[i]t is well-known in the molding art that a copolymers and a blend of two materials are substitutable alternatives" as it pertains to the claimed method of making an implantable composite bearing. The claimed invention must be examined as a whole, and obviousness cannot be based on an analysis of only a portion of the claim.

In this regard, Applicants argue that the proposed modification (i.e., the substitution of a copolymer comprising ethylene and an acrylate in lieu of a blend of UHMWPE and PMMA) is certainly not obvious in regard to the fabrication of implantable bearings. In particular, Applicants note that the use of a blend, such as those disclosed in Devanathan, is often characterized by varying local concentrations of the components of the blend. As a result, face separation at the interface of the blended layer and the adjacent polyethylene layer (e.g., UHMWPE) can occur. For example, in areas where the acrylate component of the blend is disproportionately high (and, as a result, the composition of the ethylene component of the blend is disproportionately low), retention to the adjacent polyethylene layer is reduced. This is aggravated by the tendency during

molding of the two discreet components of the blend to coalesce with their like kind (i.e., the PMMA particles tend to coalesce with other PMMA particles, while the UHMWPE particles tend to coalesce with other UHMWPE particles). Because of this, composite bearings formed by the use of blends can tend to be interfacially weak.

Applicants overcame these deficiencies by their use of a *copolymer* comprising an ethylene and an acrylate. Applicants discovered that use of such a copolymer tends to produce increased interfacial strengths thereby reducing separation of the copolymer layer from the adjacent polymer layer (e.g., UHMWPE). Unlike blends, such copolymers are relatively homogenous thereby not being subject to the varying local concentration problems associated with the use of blends. In short, Applicants have discovered that the use of a copolymer is far more than a mere "substitute" of "alternative" materials as purported by the Examiner.

As a result, the Examiner has not established a *prima facie* case of obviousness with regard to Applicants' claim 1.

Claims 2-10 and 13 are not obvious over Devanathan for at least the reasons discussed in regard to claim 1.

## CONCLUSION

In view of the foregoing remarks, it is submitted that this application is in condition for allowance. Action to that end is hereby solicited.

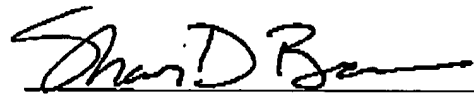
In the event that there are any questions related to this response in particular, or to the application in general, the undersigned would appreciate the opportunity to address those questions directly in a telephone interview to expedite the prosecution of this application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be

credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68188.

Respectfully submitted,

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SDB/kim

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